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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,712	06/26/2003	Stephen Dirk Pacetti	50623.273	5771

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EXAMINER

TADESSE, YEWEBDAR T

ART UNIT	PAPER NUMBER
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1734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/606,712

Applicant(s)

PACETTI, STEPHEN DIRK

Examiner

Yewebdar T. Tadesse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. The indicated allowability of claim 5 is withdrawn in view of the newly discovered reference(s) to Cassanmagnago (US 3,232,540) and Coffman (US 3,049,439).

Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 1-10 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 5, applicants claim a solvent reservoir and a polymer reservoir. It is unclear whether the claims require the reservoirs to include the claimed coating material. It is noted that reservoirs recited in these claims only require the ability to supply the polymer and solvent to the nozzle assembly. For the purpose of examination reservoirs capable of supplying solvent and polymer are assumed.

Furthermore, in claims 1, 5 and 21, it is unclear whether applicants claim a stent coating apparatus or a stent coating system. However, as shown applicants' Fig 1 a stent coating system (a group of devices, which is not a single instrument) including the supplying assembly including pumps, reservoirs and the nozzle assembly. For the purpose of examination "a stent coating system" is assumed. Clarification is necessary.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 22-23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Cassanmagnago (US 3,232,540).

As to claims 22-23, Cassanmagnago discloses (see Figs 1-2) a coating apparatus capable of coating a stent comprising a nozzle assembly having a liquid catalyst feed conduit (through duct 19', 18' and duct within nozzle 35) capable of dispensing a polymer; a paint feed conduit (through chamber 10 within nozzle 36) that is not in fluid communication with the liquid catalyst conduit capable of dispensing a solvent, wherein the paint mixes with the liquid catalyst only after the liquid catalyst and the paint dispensed from the nozzle assembly; an atomizing conduit (through duct 12 and duct within nozzle 37) that is not in fluid communication with the liquid catalyst feed conduit and the paint feed conduit and that uses atomizer air to atomize the paint and the liquid that are dispensed out from the nozzle assembly, wherein the liquid catalyst conduit is positioned within the paint feed conduit such that the paint conduit circumscribes the liquid catalyst .

As to claim 25, in Cassanmagnago the liquid feed conduit is recessed section with respect to the paint feed conduit (see Fig 1)

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 4-5 and 8 and 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Cassanmagnago (US 3,232,540) and Coffman (US 3,049,439)

As to claims 1 and 5, Cassanmagnago discloses (see Figs 1-2) a coating apparatus capable of coating a stent comprising a nozzle assembly having a liquid catalyst feed conduit (through duct 19', 18' and duct within nozzle 35) capable of dispensing a polymer; a paint feed conduit (through chamber 10 within nozzle 36) that is not in fluid communication with the liquid catalyst conduit capable of dispensing a solvent, wherein the paint mixes with the liquid catalyst only after the liquid catalyst and the paint dispensed from the nozzle assembly; an atomizing conduit (through duct 12 and duct within nozzle 37) that is not in fluid communication with the liquid catalyst feed

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conduit and the paint feed conduit and that uses atomizer air to atomize the paint and the liquid that are dispensed out from the nozzle assembly, wherein the liquid catalyst conduit is positioned within the paint feed conduit such that the paint conduit circumscribes the liquid catalyst . However, Cassanmagnago lacks teaching a coating system comprising a solvent pump that pumps a solvent from a solvent reservoir, a polymer pump that pumps a polymer from a polymer reservoir and an atomizer supply. However it is well known in the art to include a system supplying materials and atomized air to a nozzle assembly to provide the materials to the spraying device; for instance Coffman discloses (see Fig 1) a coating system comprising a pump (44) capable of pumping a solvent from a paint reservoir (12); a pump (42) capable of pumping a polymer from an additive reservoir (14); an atomizer (air supply) and a nozzle assembly(10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a coating system comprising a solvent pump that pumps a solvent from a solvent reservoir, a polymer pump that pumps a polymer from a polymer reservoir and an atomizer that atomizes the solvent and polymer in Cassanmagnago to streamline the process, increase efficiency, and use the coating solutions as they are needed while operating the apparatus.

With respect to claim 4, in Cassanmagnago the nozzle assembly enables external atomization of the materials.

With respect to claim 8, in Cassanmagnago the outlet section of the air conduit is angles relative to the liquid and paint conduits (see Figs 1-2).

As to claim 10, in Cassanmagnago the liquid feed conduit is recessed section with respect to the paint feed conduit (see Fig 1).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassanmagnago (US 3,232,540) and Coffman (US 3,049,439) as applied to claim 1 above, and further in view of Leidner et al (US 6,056,993). Cassanmagnago as modified lacks teaching a substrate support capable of supporting stent. Leidner et al discloses (see Fig 1 and column 5, lines 50-67) a stent mandrel fixture capable of securely supporting a stent during a coating process, wherein the stent mandrel-fixture is further capable of rotating or translating the stent during a coating process. It would

have been obvious to one of ordinary skill in the art at the time the invention was made to include a mandrel supporting rotating and translating a stent to suitably apply the coating onto the substrate and to completely cover coating on the surface of the substrate.

12. Claims 9 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cassanmagnago (US 3,232,540) and Coffman (US 3,049,439) as applied to claim 1 and 22 above, and further in view of Kaneko et al (US 5,249,746).

Cassanmagnago lacks teaching the solvent or polymer conduit extends out from the atomizing air conduit. Kaneko et al discloses (see Fig 5) a paint conduit (10) extending out from the atomizing air conduit (12). It would have been obvious to one of ordinary skill in the art at the time the invention was made to arrange the paint conduit extending or projecting out from the air conduit to easily suppress the diverging tendency of the paint jet stream as taught by Kaneko et al (see column 3, line 62-column 4, lines 53).

Allowable Subject Matter

13. Claims 6-7 and 21 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

14. The following is a statement of reasons for the indication of allowable subject matter: As to claims 6-7, prior art of record does not disclose or suggest a stent coating system comprising, among others, a polymer pump that pumps a polymer from a

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polymers reservoir, wherein the polymer reservoir holds a polymer and drug mixture. As to claim 21, prior art of record does not disclose or suggest a stent coating system comprising, among others, the combination of a solvent contained in a solvent reservoir; a polymer contained in a polymer reservoir and a nozzle assembly with a polymer feed conduit and a solvent conduit wherein the solvent and polymer mixes only after the polymer and solvent have been dispensed out from the nozzle assembly.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yewebdar T. Tadesse whose telephone number is (571) 272-1238. The examiner can normally be reached on Monday-Friday 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Fiorilla can be reached on (571) 272-1187. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


YTT